REMARKS

Claims 1-26 are pending. The Action states that Claims 1-14 and 16-26 are pending. Applicants respectfully submit that this is incorrect. Original Claim 15 has never been cancelled or withdrawn.

Claims 1-14 and 16-26 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,071,439 to Bawa et al. ("Bawa"). In the alternative, Claims 1-14 and 16-26 stand rejected under 35 U.S.C. §103(a) as being obvious over Bawa.

Claims 2-14 and 16-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0044514 to Richard ("Richard") and European Patent Application No. 0405284 ("Greiner") in view of "Active growth factor delivery from poly(D,L-lactide-coglycolide) foams prepared in supercritical CO_2" by David D. Hile *et al.* ("Hile") or Bawa.

Applicants respectfully traverse the rejections under 35 U.S.C. §102 and 35 U.S.C. §103 for at least the reasons set forth below.

§102 Rejections Are Overcome

A claim is anticipated under 35 U.S.C. §102 if each claimed element is found in a single prior art reference. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). There must be no difference between the claimed invention and the reference disclosure, as viewed by an ordinary artisan. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d at 1576.

Applicants' amended Claim 1 recites a method of producing a biocompatible intraluminal prosthesis for *in vivo* use, comprising:

> providing an intraluminal prosthesis having a portion thereof formed from polymeric material, wherein the polymeric material contains one or more toxic materials;
>
> ***masking one or more portions of the polymeric material***;
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> immersing the polymeric material in a densified carbon dioxide composition ***such that the toxic materials are absorbed from unmasked portions of the polymeric material*** by the densified carbon dioxide composition; and
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> removing the densified carbon dioxide composition containing the toxic materials from the polymeric material, such that the intraluminal prosthesis is suitable for *in vivo* use.

Bawa describes a method of treating contact lenses made from polymerizable materials by providing supercritical fluids to the lenses. (Bawa, Abstract). Bawa fails to describe ***masking*** one or more portions of the polymeric material of a contact lens or any other device.

The Action states that Bawa teaches masking as "blocking" at Col. 5, Lines 41-58. This passage is set forth below in its entirety.

> The present invention further contemplates the use of supercritical fluid technology to facilitate the de-blocking procedures currently used for lathed contact lenses. If a contact lens edge or surface must be altered by using a lathe, the lens is often fixed or "blocked" to a holding implement, typically using a curable wax material. This material hardens and holds the lens in place while it is rotated at high speeds against the lathe. After the lathing is complete, the lens must be removed, or "de-blocked" from the holding implement. Ecologically unfavorable materials including chlorofluorocarbons (CFCs) were widely used for such de-blocking. After the de-blocking, the lenses must then be cleaned, followed by extraction procedures as already described. It is now thought that supercritical liquids including supercritical

> CO_2 could be used to dissolve the blocking wax while at the same time cleaning the lens and also removing residual materials from the lens. (Bawa, Col. 5, Lines 41-58).

It is clear from the cited passage that "blocking" refers to securing a contact lens to a holding implement, typically using a curable wax material, so that the contact lens surface or edge can be altered via a lathe. After lathing is complete, the contact lens is removed or "de-blocked" from the holding implement via CFCs. Nothing in this passage, or in the remainder of Bawa, describes masking one or more portions of the polymeric material of an intraluminal prosthesis and immersing the polymeric material in a densified carbon dioxide composition such that toxic materials are absorbed from the unmasked portions of the polymeric material by the densified carbon dioxide composition. Masking, according to Applicants' invention, has nothing to do with securing an intraluminal prosthesis to a holding implement.

As viewed by the ordinary artisan, there is a great difference between Applicants' invention as claimed in independent Claim 1 and Bawa. Because Bawa does not disclose all of the recited elements of independent Claim 1, Claim 1 and all claims depending therefrom are not anticipated by Bawa.

Applicants' amended Claim 15 recites a method of producing a biocompatible intraluminal prosthesis for *in vivo* use, comprising:

> providing an intraluminal prosthesis having a portion thereof formed from ***erodible polymeric material*** selected from the group consisting of, surgical gut, silk, cotton, liposomes, poly(hydroxybutyrate), polycarbonate, polyacrylate, polyanhydride, polyethylene glycol, poly(ortho esters), poly(phosphoesters), polyesters, polyamides, polyphosphazenes, poly(p-dioxane), poly(amino acid), polyglactin, erodible hydrogels, collagen, chitosan, poly(lactic acid), poly(L-lactic acid), poly(D,L-lactic acid), poly(glycolic acid), poly(D-lactic-co-glycolic acid), poly(L-lactic-co-glycolic acid), poly (D,L-lactic-co-glycolic acid), poly(Є-caprolactone), poly(valerolactone), poly(hydroxy butyrate), poly(hydrovalerate), polydioxanone, poly(propylene fumarate), poly(ethyleneoxide)-poly(butylenetetraphthalate), poly(lactic acid-co-lysine), poly(L-lactic acid) and poly(Є-caprolactone) copolymers, wherein the polymeric material contains one or more toxic materials;
>
> immersing the polymeric material in a densified carbon dioxide composition such that the toxic materials are absorbed by the densified carbon dioxide composition, wherein pressure and/or temperature of the densified carbon dioxide composition is adjusted to selectively absorb toxic materials from the polymeric material;

> removing the densified carbon dioxide composition containing the toxic materials from the polymeric material;
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> lowering the density of the removed densified carbon dioxide composition such that the toxic materials entrained therein become separated therefrom; and
>
> removing the separated toxic materials, such that the intraluminal prosthesis is suitable for *in vivo* use.

Bawa fails to describe an intraluminal prosthesis having a portion formed from erodible polymeric material. The Action cites Col. 3, Lines 14-26 of Bawa, wherein "hydrogels" are discussed, as teaching erodible material. The entire paragraph from Bawa containing the cited passage is set forth below.

> Contact lens materials are formed from the polymerization product of a mixture of monomers or prepolymers. (For purposes of convenience, the term "monomer" as used hereafter shall include prepolymers.) The monomeric mixture may also include materials other than monomers that aid in the polymerization process, such as a solvent or a diluent. Contact lens materials include materials for "hard" and "soft" lenses. The hard lens classification typically includes lenses such as rigid gas permeable (RGP) contact lenses, which are generally formed of crosslinked silicone acrylate or fluorosilicone acrylate copolymers. Soft lenses include "soft" hydrogel contact lenses. Hydrogels are hydrophilic polymers that absorb water to an equilibrium value and are insoluble in water due to the presence of a crosslinked three-dimensional network. Hydrogels are generally formed of a copolymer of at least one hydrophilic monomer and a crosslinking monomer. The oydrophilicity is due to the presence of hydrophilic groups, such as alcohols, carboxylic acids, amides and sulfonic acids. The swollen equilibrated state results from a balance between the osmotic driving forces that cause the water to enter the hydrophilic polymer and the forces exerted by the polymer chains in resisting expansion. In the case of silicone hydrogel contact lenses, the copolymeric material further includes a silicone-containing monomer. Lenses in this class are generally formed of a copolymer of at least one hydrophilic monomer and a crosslinking monomer. Hydrophilic monomers include: unsaturated carboxylic acids, such as methacrylic acid and acrylic acid; (meth)acrylic substituted alcohols or glycols, such as 2-hydroxyethylmethacrylate, 2-hydroxyethylacrylate, glyceryl methacrylate, and polyethyleneglycol methacrylate; vinyl lactams, such as N-vinyl-2-pyrrolidone; and acrylamides, such as methacrylamide and N,N-dimethylacrylamide. Further examples of such hydrophilic monomers can be found in U.S. Pat. Nos. 4,153,641; 4,740,533; 5,034,461; and 5,070,215.

As is clear from the cited passage, Bawa describes soft contact lenses that include hydrogel contact lenses. Nothing in the cited passage, or anywhere else in Bawa, describes contact lenses formed from erodible material. In fact, the cited passage specifically states that

"hydrogels are hydrophilic polymers that absorb water to an equilibrium value and are ***insoluble*** in water due to the presence of a crosslinked three-dimensional network." (Bawa, Col. 3, Lines 15-18). Clearly hydrogels are not erodible if they are insoluble in water. A thorough search of the remainder of Bawa failed to locate a single instance of the word "erodible." Moreover, Applicants respectfully assert that one skilled in the art would not manufacture contact lenses from polymeric material that is erodible when in use (*i.e.*, when worn by a person), as this would affect the vision of the wearer, thus destroying the intended purpose of the contact lenses. Moreover, some eroded material may remain in the wearer's eye, which would be most undesirable .

Bawa fails to describe other recited elements of independent Claim 15. For example, Bawa fails to describe immersing polymeric material in a densified carbon dioxide composition such that the toxic materials are absorbed by the densified carbon dioxide composition, or pressure and/or temperature of the densified carbon dioxide composition being adjusted to ***selectively absorb*** toxic materials from the polymeric material. Nothing in Bawa teaches selectively absorbing toxic materials from polymeric material by adjusting pressure and/or temperature of densified carbon dioxide.

As viewed by the ordinary artisan, there is a great difference between Applicants' invention as claimed in independent Claim 15 and Bawa. Because Bawa does not disclose all of the recited elements of independent Claim 15, Claim 15 and all claims depending therefrom are not anticipated by Bawa.

§103 Rejections Are Overcome

A determination under §103 that an invention would have been obvious to someone of ordinary skill in the art is a conclusion of law based on fact. *Panduit Corp. v. Dennison Mfg. Co.* 810 F.2d 1593, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 107 S.Ct. 2187. After the involved facts are determined, the decision maker must then make the legal determination of whether the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was unknown, and just before it was made. *Id.* at 1596. The United States Patent and Trademark Office (USPTO) has the initial burden under § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness, the prior art reference or references when combined must teach or suggest *all* the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01(citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990)). As emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be **clear and particular**, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The Court of Appeals for the Federal Circuit also has stated that, to support combining or modifying references, there must be **particular** evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

Furthermore, as stated by the Federal Circuit with regard to the selection and combination of references:

> This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining

> whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion....

In re Sang Su Lee, 277 F.3d 1338, 1343 (Fed. Cir. 2002).

A. Bawa

Applicants' independent Claim 1 is patentable over Bawa. As described above, Bawa describes a method of treating contact lenses made from polymerizable materials by providing supercritical fluids to the lenses. Bawa fails to describe ***masking*** one or more portions of the polymeric material of a contact lens or any other device. The Action equates "blocking" described by Bawa with masking according to Applicants' invention. As discussed above, it is clear that "blocking" refers to securing a contact lens to a holding implement, typically using a curable wax material so that the contact lens surface or edge can be altered via a lathe. Blocking has nothing whatsoever to do with masking polymeric material as recited in Applicants' independent Claim 1. Moreover, nothing in Bawa suggests masking one or more portions of the polymeric material of an intraluminal prosthesis, then immersing the polymeric material in a densified carbon dioxide composition such that toxic materials are absorbed from the unmasked portions of the polymeric material by the densified carbon dioxide composition. In fact, Bawa teaches away from masking as recited in Applicants' independent Claim 1. Bawa describes extracting unreacted polymerized material from contact lenses to produce enhanced optical clarity. One skilled in the art would not be motivated to mask portions of a contact lens because this would leave the masked portions of the contact lens with less optical clarity than unmasked portions.

The Action has failed to provide clear and particular evidence of any suggestion of masking one or more portions of the polymeric material of an intraluminal prosthesis, then immersing the polymeric material in a densified carbon dioxide composition such that toxic materials are absorbed from the unmasked portions of the polymeric material by the densified carbon dioxide composition, as recited in Applicants' independent Claim 1.

Applicants' independent Claim 15 is patentable over Bawa. As described above, Bawa describes a method of treating contact lenses made from polymerizable materials by providing supercritical fluids to the lenses. Bawa fails to describe or suggest an intraluminal prosthesis having a portion formed from erodible polymeric material. Bawa describes soft contact lenses that include hydrogel and specifically states that "hydrogels are hydrophilic polymers that absorb water to an equilibrium value and are ***insoluble*** in water due to the presence of a crosslinked three-dimensional network." (Bawa, Col. 3, Lines 15-18). Clearly hydrogels are not erodible if they are insoluble in water. Moreover, Bawa teaches away from the use of erodible materials because one skilled in the art would not manufacture contact lenses from an erodible polymeric material. There is no motivation to provide a contact lens that erodes when in use in a person's eye.

Bawa fails to suggest other recited elements of independent Claim 15. For example, Bawa fails to teach or suggest immersing polymeric material in a densified carbon dioxide composition such that the toxic materials are absorbed by the densified carbon dioxide composition, and wherein pressure and/or temperature of the densified carbon dioxide composition is adjusted to ***selectively absorb*** toxic materials from the polymeric material. Nothing in Bawa teaches or suggests selectively absorbing toxic materials from polymeric material by adjusting pressure and/or temperature of densified carbon dioxide.

The Action has failed to provide clear and particular evidence that Bawa teaches or suggests any of the following: masking contact lenses; manufacturing contact lenses from erodible material; or selectively absorbing toxic materials from contact lens polymeric material by adjusting pressure and/or temperature of densified carbon dioxide. As such, Applicants respectfully request withdrawal of the present rejections based on Bawa under 35 U.S.C. §103.

B. Richard, Greiner, Hile

The Action states that Claims 2-14 and 16-26 are unpatentable over the combination of Richard, Greiner and Hile, or alternatively, Richard Greiner and Bawa. Because Applicants' independent Claims 1 and 15 are not rejected based on the above combinations of references, Applicants submit that the claims depending from independent Claims 1 and 15,

Claims 2-14 and 16-26, should by definition be patentable over the combinations of the references. Nonetheless, Applicants address each of the cited references.

Richard describes a medical device having a coating containing a releasable therapeutic and a method of coating a medical device with a releasable therapeutic. The Action concedes that Richard fails to disclose "attendant toxics, or cosolvents, or masking." (Action, Page 4).

Greiner describes a method of impregnating a catheter, made of polymeric material, with a pharmaceutical. The catheter is immersed into a saturated solution of a pharmaceutical in a solvent. The saturated solution serves as a swelling agent and swells the polymeric material of the catheter. The catheter is contacted with the swelling agent at or near supercritical pressure and temperature of the solvent. The pressure is then reduced from supercritical pressure to release the solvent from the catheter, thereby leaving the pharmaceutical impregnated within the catheter. Greiner fails to teach or suggest immersing a polymeric material in a densified carbon dioxide composition such that toxic materials are ***absorbed*** (or selectively absorbed) by the densified carbon dioxide composition, as recited in Applicants' independent Claims 1 and 15. In fact, the Action appears to concede that Greiner fails to teach or suggest absorbing toxic materials with densified carbon dioxide: "However, Greiner does not focus, although discloses (p.3, col. 3) - methylene chloride - alcohols on removable of toxics." (Action, Page 4). Greiner fails to teach or suggest masking one or more portions of polymeric material of a catheter and impregnating only unmasked portions thereof.

Hile describes a method, using supercritical carbon dioxide, for the production of microporous copolymer foams containing encapsulated proteins. Foams generated as aqueous protein emulsions in a polymer-solvent solution are saturated with carbon dioxide at supercritical conditions, and then suddenly supersaturated at ambient conditions causing bubble nucleation and precipitation of the polymer. Proteins contained in the water phase of the emulsion are encapsulated within the foams, including basic fibroblast growth factor (bFGF). Hile fails to teach or suggest immersing polymeric material in densified carbon dioxide such that toxic materials are ***absorbed*** by the densified carbon dioxide. In contrast, Hile describes removing methylene chloride from the polymeric material by pressurizing a

pressure cell with CO_2 so as to saturate the polymer with CO_2 and extract (*i.e.*, force out) the methylene chloride. Hile does not teach or suggest that the methylene chloride is absorbed by the CO_2, as recited in Applicants' independent Claims 1 and 15. In addition, Hile specifically states that "residual methylene chloride levels in foams prepared in CO_2 were beyond limits imposed by the US Pharmacopeia implying that further solvent removal would be required for these devices prior to in vivo use." (Hile, Page 184). Accordingly, the Hile method alone does not produce a device that is suitable for *in vivo* use.

Applicants' independent Claim 15 recites a method of producing a biocompatible intraluminal prosthesis for *in vivo* use that includes immersing polymeric material in a densified carbon dioxide composition such that toxic materials from the polymeric material are absorbed by the densified carbon dioxide composition, wherein pressure and/or temperature of the densified carbon dioxide composition is adjusted to ***selectively absorb*** toxic materials from the polymeric material. Hile fails to teach providing an intraluminal prosthesis. In addition, Hile fails to teach immersing polymeric material in densified carbon dioxide such that toxic materials are ***absorbed*** by the densified carbon dioxide. Hile fails to teach or suggest ***selectively*** absorbing toxic materials from the polymeric material of an intraluminal prosthesis via the adjustment of temperature and/or pressure of densified carbon dioxide. Hile fails to teach or suggest masking microporous copolymer foams during the production thereof and removing toxic materials only from unmasked portions of the foams.

The combination of Richard, Greiner and Hile fails to teach or suggest all of the recitations of Applicants' independent Claims 1 and 15. Richard, Greiner and Hile all fail to teach or suggest masking polymeric material and removing toxic materials only from unmasked portions. Richard, Greiner and Hile all fail to teach or suggest immersing a polymeric material in a densified carbon dioxide composition such that toxic materials are ***absorbed*** by the densified carbon dioxide composition. In fact, Hile teaches away from the absorption of toxic materials by describing removing methylene chloride from polymeric material by forcing out the methylene chloride under pressure. Hile does not teach or suggest that the methylene chloride is absorbed by the CO_2, as recited in Applicants' independent Claims 1 and 15.

Moreover, Richard, Greiner and Hile all fail to teach or suggest selectively absorbing toxic materials from polymeric material as recited in Applications' independent Claim 15.

The combination of Richard, Greiner and Bawa also fails to teach or suggest all of the recitations of Applicants' independent Claims 1 and 15. As discussed above, Bawa fails to describe ***masking*** one or more portions of polymeric material as recited in Applicants' independent Claim 1. Moreover, nothing in Bawa suggests masking one or more portions of the polymeric material of an intraluminal prosthesis and then immersing the polymeric material in a densified carbon dioxide composition such that toxic materials are absorbed from the unmasked portions of the polymeric material by the densified carbon dioxide composition. In fact, as discussed above, Bawa teaches away from masking. Bawa describes extracting unreacted polymerized material from contact lenses to produce enhanced optical clarity. One skilled in the art would not be motivated to mask portions of a contact lens such that portions of the contact lens have less optical clarity than other portions.

As discussed above, Bawa fails to describe or suggest an intraluminal prosthesis having a portion formed from ***erodible*** polymeric material. Bawa describes soft contact lenses that include hydrogel contact lenses and specifically states that hydrogels are hydrophilic polymers that absorb water to an equilibrium value and are ***insoluble*** in water. Moreover, Bawa teaches away from the use of erodible materials because one skilled in the art would not manufacture contact lenses from an erodible polymeric material. There is no motivation to provide a contact lens that erodes when in use in a person's eye.

As discussed above, Bawa fails to teach or suggest immersing polymeric material in a densified carbon dioxide composition such that the toxic materials are absorbed by the densified carbon dioxide composition, and ***wherein pressure and/or temperature of the densified carbon dioxide composition is adjusted to selectively absorb toxic materials from the polymeric material.*** Nothing in Bawa teaches or suggests selectively absorbing toxic materials from polymeric material by adjusting pressure and/or temperature of densified carbon dioxide.

None of the references cited by the Action, alone or in combination, teach or suggest all of the recitations of Applicants' independent Claims 1 and 15. Accordingly, Applicants respectfully request withdrawal of the present rejections under 35 U.S.C. §103.

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

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